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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,448	03/20/2002	Katy Drieu	00537-194002	4565
37903	7590	01/27/2005	EXAMINER	
DAWN JANELLE AT BIOMEASURE INC. 27 MAPLE STREET MILFORD, MA 01757			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/018,448	<b>Applicant(s)</b> DRIEU ET AL.	
	<b>Examiner</b> Gollamudi S Kishore, Ph.D	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-4-02</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Applicant's response to the election requirement dated 9-24-04 is acknowledged.

Applicant amends the claims to depend from claim 1 and argues that all claims are drawn to a method of treating cancer. In view of the amendment and the argument, the previous election requirement is withdrawn.

Claims included in the prosecution are 1-25.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro inhibition of MDA –231 cells by Ginkgolide B, does not reasonably provide enablement for the generic “a method of combating cancer by Ginkgolide B or Ginkgo biloba extracts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Cancer as is well known in the art is a generic term used for multitudes of different cell proliferative diseases and there is no specific drug which can be used to treat all forms of cancer. Just because a specific component is effective in the expression of a specific gene or effective in in vitro inhibition of a specific cancer cell cultures, one cannot draw a conclusion that either an extract containing that specific compound or the specific compound itself is effective in the in vivo treatment of various cancers. Instant

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specification lacks adequate description to come to that conclusion. Broad claims must have broad basis of support in the specification. In the absence of such support, claims must be limited to the in vitro effectiveness of Ginkgolide B in inhibiting MDA-231 cells in culture.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

2. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 42 08 868 or EP 0 359 951 (both are of record).

DE 42 08 868 discloses a method of treatment of cancer using Ginkgo boloba extracts (abstract and col. 1 and claims).

Similarly EP discloses a method of treatment of cancer using Ginkgo boloba extracts (see entire patent).

The mechanism by which the composition of the prior art functions has no patentable significance since it is the inherent effect of the prior art extract.

The above rejections would be reconsidered upon the review of the English translations.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1-9, 12-13 and 15-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogerty 6,316,690.

Fogerty discloses the anti-tumor activity of Ginkgo biloba extract is known in the art. The tumors discussed in specific include hepatic, colon, leukemia, lymphoma, glioma, breast, prostate, pancreas, bladder, melanoma and lung (col. 12, line 44 through col. 13, line 27).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.


5. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty cited above.

Fogarty teaches a transgenic *Drosophila melanogaster* as the model to predict the ability of a compound's effectiveness in the treatment of cancer. One of the ingredients used by Fogarty is Ginkgo biloba extract. Based on this model taught by Fogarty combined with the art known anti-tumor activity of Ginkgo biloba extracts also taught by Fogarty, it would have been obvious to one of ordinary skill in the art to use Ginkgo extracts to treat various forms of cancer, with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK